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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,207	08/28/2003	Aaron W. Janke	279.093US3	9733

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
11/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,207	JANKE ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The finality of the rejection of the last Office action has been withdrawn, although this office action is made final since the RCE of 7/31/06 did not contain any new claim limitations and the 103 rejections relying on common knowledge have only incorporated the evidence based on Applicant's rebuttal of the common knowledge rejection.

According to MPEP 2144.03D, "[I]f the examiner adds a reference in the next Office action after applicant's rebuttal, and the newly added reference is added only as directly corresponding evidence to support the prior common knowledge finding, and it does not result in a new issue or constitute a new ground of rejection, the Office action may be made final. If no amendments are made to the claims, the examiner must not rely on any other teachings in the reference if the rejection is made final. If the newly cited reference is added for reasons other than to support the prior common knowledge statement and a new ground of rejection is introduced by the examiner that is not necessitated by applicant's amendment of the claims, the rejection may not be made final.

Election/Restrictions

Claims 9-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the telephone conversation of 3/30/06.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (4886074) in view of Dutcher et al (5217028).

Bisping discloses the claimed invention in figures 1-5 with electrode, 3, guiding mechanism, 8, movement assembly, 5, 9, and 3, with piston, 5, base, 3, knob, 9 or 12, slot, 10 or 11a, and helix, 7, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. Dutcher teaches that it is known to include on a lead having a fixation helix a mesh (e.g. 146, col. 5) at the electrode end and a non-soluble coating containing a drug on a portion of the exterior surface of the lead (e.g. col. 2, lines 45-65, figure 5, 138, or 138 and 133) to allow heart tissue to securely fixate to the lead when implanted and allow the helix to elude drugs to prevent inflammation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Bisping, with a mesh

screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, as taught by Dutcher since it would provide a heart lead with a mesh screen disposed on the electrode tip to provide the predictable results of allowing fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it would provide a heart lead with a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide the predictable results of a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation due to the helix.

Claims 1-5, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (4886074) in view of Rockland et al (4010758) and (Altman, 5551427, or Hoffman, 5902329).

Bisping discloses the claimed invention in figures 1-5 with electrode, 3, guiding mechanism, 8, movement assembly, 5, 9, and 3, with piston, 5, base, 3, knob, 9 or 12, slot, 10 or 11a, and helix, 7, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. Rockland teaches that it is known to include on a lead having a fixation helix a mesh (e.g. 28, column 8) at the electrode end and a non-soluble coating on a portion of the exterior surface of the helix (e.g. silicone, figure 2b, 2c, col. 5) to allow heart tissue to securely

and quickly fixate to the lead when implanted and allow the helix to provide a better electrical field and the system to use less power. Altman or Hoffman teaches that it is known to include in the insulation of a fixation device, the use of an active ingredient, such as an anti-implammatant to reduce irritability and inflammation due to the fixation device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Bisping, with a mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating as taught by Rockland, and with an active ingredient, such as an anti-inflammatant, as taught by Altman or Hoffman since it would provide a heart lead with a mesh screen disposed on the electrode tip to provide the predictable results of allowing fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it would provide a heart lead with a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide the predictable results of a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing and use less system power, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation due to the helix.

Claims 1, 2, 3, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (4624265) in view of Dutcher et al (5217028).

Grassi discloses the claimed invention in figure 4 with electrode, 21, guiding mechanism, 20, movement assembly, 14 and 17, seal, 16, base, 17, and piston, 14 between seals 16, and

helix, 15, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. Dutcher teaches that it is known to include on a lead having a fixation helix a mesh (e.g. 146, col. 5) at the electrode end and a non-soluble coating containing a drug on a portion of the exterior surface of the lead (e.g. col. 2, lines 45-65, figure 5, 138, or 138 and 133) to allow heart tissue to securely fixate to the lead when implanted and allow the helix to elude drugs to prevent inflammation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, as taught by Dutcher since it would provide a heart lead with a mesh screen disposed on the electrode tip to provide the predictable results of allowing fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it would provide a heart lead with a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide the predictable results of a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation due to the helix.

Claims 1, 2, 3, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (4624265) in view of Rockland et al (4010758) and (Altman, 5551427, or Hoffman, 5902329).

Grassi discloses the claimed invention in figure 4 with electrode, 21, guiding mechanism, 20, movement assembly, 14 and 17, seal, 16, base, 17, and piston, 14 between seals 16, and helix, 15, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. Rockland teaches that it is known to include on a lead having a fixation helix a mesh (e.g. 28, column 8) at the electrode end and a non-soluble coating on a portion of the exterior surface of the helix (e.g. silicone, figure 2b, 2c, col. 5) to allow heart tissue to securely and quickly fixate to the lead when implanted and allow the helix to provide a better electrical field and the system to use less power. Altman or Hoffman teaches that it is known to include in the insulation of a fixation device, the use of an active ingredient, such as an anti-implammatant to reduce irritability and inflammation due to the fixation device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating as taught by Rockland, and with an active ingredient, such as an anti-inflammatant, as taught by Altman or Hoffman since it would provide a heart lead with a mesh screen disposed on the electrode tip to provide the predictable results of allowing fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it would provide a heart lead with a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide the predictable results of a

biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing and use less system power, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation due to the helix.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over either modified Grassi rejected above in view of Bisping, Jammet (5447534), or Ocel et al (5837006).

Modified Grassi discloses the claimed invention except for the knob and slot mating with the knob to form a stop mechanism. Bisping, Jammet, or Ocel discloses the use of a knob and slot mating with the knob to form a stop mechanism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by the modified Grassi, with a knob and slot mating with the knob to form a stop mechanism as taught by Bisping, Jammet, or Ocel since it was known in the art that heart leads use a knob and slot mating with the knob to form a stop mechanism to provide the predictable results of preventing the helix from being retracted further into the lead and causing damage to the lead.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over either modified Bisping or either modified Grassi as applied to claim 1 above and further in view of Ocel (5837006) or Vachon (5531780). The modified Bisping or Grassi discloses the claimed invention with a traveling helix through a mesh screen except for the groove guide. Ocel or

Vachon teaches that it is known to provide groove guides on the distal end of the housing to allow the helix to be easily extended and to guide the helix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the mesh and helical lead as taught by the modified Bisping or Grassi, with a groove guide as taught by Ocel or Vachon since it was known in the art that leads with traveling helixes use a groove guide to provide the predictable results of guiding the helix through the distal end of the lead body/mesh to smoothly guide the helix to exit and enter the lead body.

Response to Arguments

Applicant's arguments filed 7/31/06 and 11/9/07 have been fully considered but they are persuasive. The argument that the drug plug, 138, of Dutcher "cannot be properly construed as a coating of non-soluble insulating material. Accordingly, even if combined with Bisping, the combined structure does not read on the claimed: non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient" is not persuasive since the Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The Applicant has only argued that Dutcher does not have the claimed limitation, but does not state why Dutcher does not have the claimed limitation or rebut the Examiners previous discussion of Dutcher in the office action of 8/4/2006. Specifically, Dutcher shows in figures 5, 8, and 9, the plastic drug plug, 138/238, covering/coating a portion of the outer surface of the helix, wherein the drug plug also contains an active ingredient. See col. 4, lines 46-68 or col. 6, lines 32-36. In addition, Dutcher shows

the helix also containing another insulative coating, 133 or 233 (e.g. col. 3, line 57), that conforms to an outer surface of the helix and contains an active ingredient from drug plug, 138, due to the migration of the drug from the plug or touching of the plug to insulative coating, 133 or 233.

The argument that Altman is not explicit that the polymer is non-soluble because Altman states there is a biodegradation of the polymer is not persuasive since Altman discloses other embodiments where the polymer is non-soluble. Specifically, Altman states in column 15, lines 5-12 the use of non-soluble polymers as the insulative/non-conductive materials and discusses in column 10, lines 25-30 how a non-soluble insulative coating contains a drug similar to what is disclosed in US patent 5342628.

The argument that Altman's coatings are directed toward "effective elimination of an arrhythmogenic site" in contrast to Bisping which relates to an implantable electrode type lead assembly and therefore it appears the two are generally used for different purposes is not persuasive since both Altman and Bisping are in the same field of endeavor, i.e. fixation helixes used to screw into the heart.

The argument that Hoffman does not have a non-soluble coating on a helix is not persuasive since Hoffman was used to show the use of an active ingredient/drug in a non-soluble coating for use on a fixation device (i.e. the tines of Hoffman).

The argument that Appellant believes the office action has provided insufficient motivation to modify the Bisping reference is not persuasive since the Examiner has provided motivation for all the claimed elements as seen in the 103 rejections above. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of

the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In addition, in view of the recent KSR International Co. Vs. Teleflex Inc. Supreme Court Decision, the combination of well known familiar elements, such as the helical lead of Bisping or Grassi, with the mesh and helical insulative coating with active ingredient as set forth in the prior art of Dutcher, Altman, Struble, Heil, Hoffman, etc. would yield the predictable results of providing a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

The argument in the last full paragraph on page 10 that the office action merely applies hindsight analysis to find obviousness is not persuasive since it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The Applicant's arguments that they cannot find in Bisping the fixation helix including a non-soluble insulating material with active ingredient coated on at least a portion of the helix's

outer surface and that the discussion for claim 1 is incorporated herein by reference are not persuasive. Please see the Examiners discussion for claim 1 above (and incorporated herein) as to why the arguments are not persuasive.

The Applicant argues that they cannot find in Grassi the fixation helix including a non-soluble insulating material with active ingredient coated on at least a portion of the helix's outer surface and further argues the same position in regards to Dutcher and Altman as discussed in the Applicant's arguments for claim 1 in view of Bisping. Please see the Examiners discussion for claim 1 above (and incorporated herein) as to why the arguments are not persuasive.

The Applicant's arguments that they cannot find in Grassi the fixation helix including a non-soluble insulating material with active ingredient coated on at least a portion of the helix's outer surface and that the discussion for claim 1 is incorporated herein by reference are not persuasive. Please see the Examiners discussion for claim 1 above (and incorporated herein) as to why the arguments are not persuasive.

The Applicant's argument that the Office Action has provided insufficient motivation to modify the cited reference of Grassi is not persuasive since the Examiner has provided motivation for all the claimed elements as seen in the 103 rejection above. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In addition, in view of the recent KSR International Co. Vs. Teleflex Inc. Supreme Court Decision, the

combination of well known familiar elements, such as the helical lead of Grassi, with the knob and slot mating with the knob to form a stop mechanism as set forth in the cited prior art of Bisping, Ocel, Jammet, etc. would yield the predictable results of preventing the helix from being retracted further into the lead and causing damage to the lead.

The Applicant's argument that the Office Action has provided insufficient motivation to modify the cited reference of Grassi or Bisping is not persuasive since the Examiner has provided motivation for all the claimed elements as seen in the 103 rejection above. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In addition, in view of the recent KSR International Co. Vs. Teleflex Inc. Supreme Court Decision, the combination of well known familiar elements, such as the helical lead of Bisping or Grassi, with a groove guide as set forth in the prior art of Vachon, Ocel, etc. would yield the predictable results of guiding the helix through the distal end of the lead body/mesh to smoothly guide the helix to exit and enter the lead body.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under

37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
11/13/08